

### REMARKS

The Examiner rejected claims 1-22. Claims 1, 3, 4, 6-10, and 12-22 have been cancelled herein without prejudice. Claims 2, 5, and 11 have been amended herein, and new claims 23-38 have been added. Thus, claims 2, 5, 11, and 23-38 are pending.

Claim 2 has been amended herein to depend from claim 5. Claims 5 and 11 have been amended herein to be written in independent form, incorporating the language of originally presented claim 1. Claims 23-38 recite methods for making viral vectors. No new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request allowance of claims 2, 5, 11, and 23-38.

#### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner stated that "the nucleic acid sequences as claimed has [sic] been defined only by a statement of function that broadly encompasses all destabilizing sequences on an mRNA transcript which conveyed no distinguishing information about the identity of the claimed genetic material, such as its relevant structural or physical characteristics."

Applicants respectfully disagree. A person having ordinary skill in the art at the time Applicants filed would have understood from Applicants' specification that Applicants invented the previously claimed subject matter. To further prosecution, however, claims 1, 3, 4, 6-10, and 12-22 have been cancelled herein without prejudice. In addition, claims 5 and 11 have been amended herein to be written in independent form, and claim 2 has been amended herein to depend from claim 5. Claim 5 recites that the heterologous destabilizing element is the 3' untranslated region of the tumor necrosis factor alpha gene, while claim 11 recites that the heterologous destabilizing element is the 3' untranslated region of the urokinase plasminogen activator receptor gene. Clearly, a person having ordinary skill in the art reading Applicants'

specification would have appreciated that viral vectors reciting such heterologous destabilizing elements are fully described.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 2, 5, and 11 under 35 U.S.C. §112, first paragraph.

With respect to new claims 23-38, Applicants note that a person having ordinary skill in the art at the time Applicants filed would have understood from Applicants' specification that Applicants invented the recited methods. This is particularly true given that Applicants' specification describes that multiple viral vectors that can be used including adenoviruses, vaccinia viruses, herpes viruses, reoviruses, Newcastle disease viruses, retroviruses, adeno-associated viruses, and Sindbis viruses. See, e.g., page 6, lines 18-21 of Applicants' specification. In addition, Applicants' specification describes not one destabilizing element as the Examiner appears to contend but rather multiple destabilizing elements. For example, Applicants' specification describes the following destabilizing elements: the 3'UTR of the COX-2 gene, the 3' UTR of the vascular permeability factor/vascular endothelial growth factor gene, the 3' UTR of the urokinase plasminogen activator receptor gene, and the 3' UTR of the tumor necrosis factor alpha gene. See, e.g., page 6, lines 23-24 and page 8, lines 1-7 of Applicants' specification. Moreover, Applicants' specification describes that a destabilization element typically contains at least a portion of a 3' UTR that contains AU rich sequences. See, e.g., page 6, lines 17-18 of Applicants' specification. Thus, Applicants' specification adequately describes the subject matter recited in new claims 23-38.

The Examiner also rejected claims 17-22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully disagree. A person having ordinary skill in the art at the time Applicants filed would have been able to carry out the previously recited methods without undue experimentation. To further prosecution, however, claims 17-22 have been cancelled herein without prejudice. Thus, this rejection is moot.

Rejections under 35 U.S.C. § 102(b)

The Examiner rejected claims 1, 2, 9, 10, and 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by the WO 98/56939 reference. Applicants respectfully disagree. To further prosecution, however, claims 1, 9, 10, and 22 have been cancelled herein without prejudice. In addition, claim 2 has been amended herein to depend from claim 5. Thus, this rejection is moot.

The Examiner rejected claims 1, 2, 9, 10, and 12-13 under 35 U.S.C. § 102(b) as allegedly being anticipated by the Boast *et al.* reference (*Human Gene Ther.*, 10:2197-2208 (1999)). Applicants respectfully disagree. To further prosecution, however, claims 1, 9, 10, and 12-13 have been cancelled herein without prejudice. In addition, claim 2 has been amended herein to depend from claim 5. Thus, this rejection is moot.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 6-8, 12-15, and 17-19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the WO 98/56939 reference in view of the Sheng *et al.* reference (*J. Biol. Chem.*, 275:6628-6635 (2000)) and the Curiel reference (*Clin. Cancer Res.*, 6:3395-3399 (2000)). Applicants respectfully disagree. To further prosecution, however, claims 6-8, 12-15, and 17-19 have been cancelled herein without prejudice. Thus, this rejection is moot.

Applicant : Richard G. Vile et al.  
Serial No. : 10/533,613  
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Page : 8 of 8

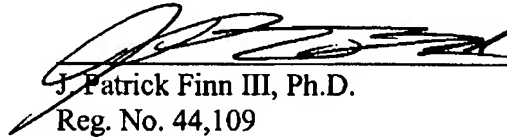
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### CONCLUSION

Applicants submit that claims 2, 5, 11, and 23-38 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050.

Respectfully submitted,

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J. Patrick Finn III, Ph.D.  
Reg. No. 44,109

Fish & Richardson P.C.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

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